UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Roxane Laboratories, Inc,

Plaintiff,

-v- **Case No. 2:12–cv–312**

Abbott Laboratories, *et al.* **Judge Michael H. Watson**

Defendants.

OPINION AND ORDER

In this patent action, Plaintiff Roxane Laboratories, Inc. seeks declaratory judgment invalidating two patents now held by Defendant AbbVie Inc., which were originally owned by Defendant Abbott Laboratories. Plaintiff objects to a discovery order by the Magistrate Judge, ECF No. 105. In addition, the parties jointly move to consolidate this action with a related case, ECF No. 110. For the reasons which follow, the Court overrules Plaintiff's objections and grants the parties' motion to consolidate the cases.

I. BACKGROUND

Both Plaintiff Roxane Laboratories, Inc. (" Roxane" or "Plaintiff") and Defendant Abbott Laboratories ("Abbott") are international corporations that manufacture pharmaceuticals. Defendant AbbVie Inc. ("AbbVie") was created to take over Abbott's research-based, proprietary pharmaceutical business and began as a wholly owned subsidiary of Abbott. Both parties agree that AbbVie now holds the patents at issue,

but Abbott remains a Defendant because it is unclear whether AbbVie has assumed liability for any attorneys' fees that may be awarded in this case. Order 4, ECF No. 55.

The patents at issue in the instant litigation concern the drug Norvir. Norvir is sold by Abbott throughout the United States as a treatment for Human Immunodeficiency Virus ("HIV"). Ritonavir, the active ingredient in Norvir, has been shown to boost the effectiveness of other HIV treatments, including drugs known as protease inhibitors. Other HIV drugs would be toxic in dosage amounts necessary for them to be effective in treating HIV, but ritonavir allows them to be administered in lower amounts that are safe and effective. In this suit, Roxane challenges U.S. Patent Nos. 7,148,359 ("'359 patent") and 7,364,752 ("'752 patent") which cover the physical form of ritonavir in Norvir. AbbVie also holds other patents involving Norvir, including U.S. Patent Nos. 5,648,497 ("'497 patent"), 6,037,157 ("'157 patent"), and 6,703,403 ("'403 patent"). The '497 patent concerns the chemical composition ritonavir. The '157 and '403 patents cover Norvir's interaction with the human body.

On April 10, 2012 at 4:25 p.m., Roxane filed suit in this Court against Abbott seeking declaratory judgment that Abbott's '359 and '752 patents are invalid. At 11:51 p.m. on that same day, Abbott filed suit in the District of Delaware alleging Roxane's Abbreviated New Drug Application to market a generic version of Norvir infringed Abbott's '359, '752, '497, '157 and '403 patents.

Abbott moved to dismiss or transfer this action to Delaware, and the Court denied Abbott's motion. Subsequently, Roxane moved to enjoin Abbott from proceeding in Delaware, and the Court denied that motion. On June 18, 2013, the United States District Court for the District of Delaware granted Roxane's request to

transfer the Delaware action and transferred *AbbVie Inc. v. Roxane Laboratories Inc.*, No. 2:13–cv–645., to the Southern District of Ohio where it was randomly assigned to Judge Graham.

II. OBJECTIONS TO ORDER TO COMPEL DISCOVERY

In its motion to compel, Defendants sought documents related to Plaintiff's "investigation of and/or decision not to pursue: (1) a ritonavir oral solution and/or capsule formulation and (2) a non-solid dispersion tablet formulation of ritonavir." Mot. Compel 1, ECF No. 82. Defendants argued the documents described are relevant to objective evidence of nonobviousness of the inventions claimed in the '359 and '752 patents, including the secondary considerations of copying, commercial success, and benefits of the claimed inventions. Mem. Mot. Compel 2, ECF No. 83.

Holding the documents were relevant to the secondary consideration of commercial success of the Norvir tablets, Magistrate Judge King ordered Plaintiff to "produce documents in its possession, custody, or control that relate to its investigation of and/or decision not to pursue: (1) a ritonavir oral solution and/or capsule formulation and (2) a non-solid dispersion tablet formulation of ritonavir." Order 10, ECF No. 100.

A. Standard of Review

Upon objection by a party, the district court must modify or set aside any portion of a magistrate judge's non-dispositive pretrial order that is clearly erroneous or contrary to law. 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a). Discovery matters are generally non-dispositive and, therefore, the clearly erroneous or contrary to law standard applies. *Chesher v. Allen*, 122 F. App'x

184, 186 (6th Cir. 2005). A finding of fact is clearly erroneous where it is against the clear weight of the evidence or where the court is of the definite and firm conviction that a mistake has been made. *Graff v. Havernill N. Coke Co.*, No. 1:09–cv–670, 2011 WL 1598760, at *2 (S.D. Ohio April 28, 2011). A conclusion of law is contrary to law if the magistrate judge has misinterpreted or misapplied applicable law. *Id.*

B. Controlling Law

Federal Rule of Civil Procedure 26 allows parties to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.*

The Magistrate Judge concluded that the documents Defendants request are relevant to the consideration of obviousness. An invention is obvious and, therefore, the patent invalid, "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is a question of law with several underlying factual inquiries, including "(1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others" to meet the same need.

In re Antor Media Corp., 689 F.3d 1282, 1293 (Fed. Cir. 2012).

The Magistrate Judge specifically based her order to compel on the relevancy of the requested documents to the secondary factor of commercial success. The secondary factors are used as objective evidence of nonobviousness because they indicate that the invention is new and needed. *See, e.g., Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012) (other secondary factors include initial skepticism of the invention, unexpected and superior results, wide spread acceptance in the field and copying of the invention). Commercial success of an invention may be relevant to obviousness if there is a nexus between the claimed invention and the commercial success. *Tokai Corp. v. Easton Enter., Inc.*, 632 F.3d 1258, 1369 (Fed. Cir. 2011). "If commercial success is due to an element in the prior art, no nexus exists." *Id.*

C. Plaintiff's Objections

Plaintiff's first objection is that the Magistrate Judge erred in reaching the legal conclusion that information related to different ritonavir formulations is relevant to the commercial success of the patents involved in this suit. Plaintiff argues the Magistrate Judge erred in concluding a patenee does not need to demonstrate a nexus between the claimed invention and the commercial success to obtain discovery of otherwise relevant information. Plaintiff also argues it has no information on sales of other forms of ritonavir because it has never sold any form of ritonavir, and Defendants are the only manufacturers to commercialize different ritonavir formulations and, therefore, already have any information on the commercial success of other formulations. Finally, Plaintiff argues the fact Defendants did not list the other products in response to interrogatories

that required them to articulate their grounds for their allegation of nonobviousness is evidence the other ritonavir formulations are not relevant to obviousness.

The Court finds the Magistrate Judge was correct to conclude a patenee does not need to demonstrate a nexus between the invention claimed in the patent and commercial success of the product in order to obtain discovery commercial success. The nexus between the invention and commercial success controls whether commercial success supports a finding of nonobviousness at trial. At the discovery stage, the question is simply whether the discovery request is reasonably calculated to lead to the discovery of information which demonstrates a nexus between the claimed invention and the commercial success. *Am. Std. Inc. v. Pfizer Inc.*, 828 F.2d 734, 741–42 (Fed. Cir. 1987). Accordingly, the Magistrate Judge employed the correct legal standard.

There must, however, be "some relationship" between the invention claimed in the disputed patent and the sales data sought. *Id.* According to Defendants and the Magistrate Judge, that connection is that the tablets contained ritonavir, and commercial success of Defendants' ritonavir tablets must be considered in relation to the success of competing formulations of ritonavir. This is logical because in order to isolate whether the invention claimed in the patents caused the commercial success of Defendants' Norvir tablets, a court may need to consider other ritonavir options on the market.

However, Plaintiff's second argument is that any market research it did on the other formulations of ritonavir cannot reasonably lead to new evidence for comparison because it never actually sold any formulations of ritonavir, and only Defendants market

the other formulations of ritonavir. Defendants respond that they are seeking Plaintiff's internal documents concerning Defendants' sales of ritonavir products because they will provide direct evidence of Plaintiff's own recognition of the ritonavir tablet's success relative to other formulations. The Magistrate Judge did not misinterpret or misapply applicable law in determining information related to Plaintiff's investigation of other ritonavir formulations could reasonably lead to the discovery of evidence of such an admission. This admission in turn could support Defendants' contention the claimed inventions were not obvious.

Plaintiff's final argument is simply a new attempt to argue the information Defendants seek is not relevant because Defendants did not identify the other ritonavir formulations in their responses to interrogatories concerning obviousness. Plaintiffs did not raise this argument in its response to the motion to compel, and the Court will not consider it now. *Murr v. United States*, 200 F.3d 895, 902 n.1 (6th Cir. 2000) (district court need not consider argument not raised before magistrate judge). In addition, Defendants' responses to the interrogatories do not foreclose seeking other information in discovery. Accordingly, the Court overrules Plaintiff's first objection.

Plaintiff's second objection is that the Magistrate Judge's order to compel discovery was overbroad. Plaintiff argues that even if the sales data concerning why Plaintiff decided not to pursue other forms of ritonavir is relevant to the litigation, the Magistrate Judge's order potentially allows discovery into technical and business documents and is not limited in time. Defendants respond that the Magistrate Judge's Order included discovery into sales, technical, and business documents because they

are all relevant to the issues of commercial success and the benefits of the claimed invention. The Magistrate Judge did not err in permitting discovery into all documents related to Plaintiff's reason for not pursuing other forms of ritonavir because scientific and marketing documents, in addition to sales documents, could support Defendants' claims of commercial success based on the inventions protected by the patents. Isolating the effect of the claimed inventions on Norvir's commercial success is complicated and many different types of documents may be relevant to determine the connection between the invention and the success. The information will necessarily be limited by the time period in which Plaintiff explored other forms of ritonavir. Accordingly, the Magistrate Judge did not misapply law in ordering the disclosure of all "documents in [Plaintiff's] possession, custody, or control that relate to its investigation of and/or decision not to pursue: (1) a ritonavir oral solution and/or capsule formulation and (2) a non-solid dispersion tablet formulation of ritonavir." Order 10, ECF No. 100. The Court, therefore, overrules Plaintiff's second objection.

III. MOTION TO CONSOLIDATE

Federal Rule of Civil Procedure 42 allows a court to consolidate cases "[i]f actions before the court involve a common question of law or fact." Fed. R. Civ. P. 42(a)(2). As Case Numbers 2:12–cv–312 and 2:13–cv–645 both involve the '359 patent and '752 patent, the cases involve a common question of law or fact. In recognition of this overlap, the undersigned and Judge Graham have signed a related case memorandum reassigning Case Number 2:13–cv–645 to the undersigned. The Court now grants the parties' motion to consolidate the cases, ECF No. 110.

IV. CONCLUSION

For the above reasons, the Court **OVERRULES** Plaintiff's objections, ECF No. 105, and **GRANTS** the parties' motion to consolidate Case Numbers 2:12–cv–312 and 2:13–cv–645, ECF No. 110.

IT IS SO ORDERED.

MICHAEL H. WATSON, JUDGE
UNITED STATES DISTRICT COURT